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No. 89-1279

IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

PACIFIC MUTUAL LIFE INSURANCE COMPANY,
Petitioner,

v.

CLEOPATRA HASLIP, *et al.*,
Respondents.

On Writ of Certiorari to the Supreme Court of Alabama

BRIEF OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION AND THE AMERICAN MEDICAL ASSOCIATION, AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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May 31, 1990

WILSON - EPES PRINTING CO., INC. 789-0096 - WASHINGTON, D.C. 20001

QUESTION PRESENTED

Whether an award of punitive damages violates the Due Process Clause of the Fourteenth Amendment.

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INTEREST OF THE *AMICI CURIAE*

The Pharmaceutical Manufacturers Association (PMA) is a voluntary, nonprofit association representing more than 100 research-intensive companies engaged in the discovery and development of prescription pharmaceutical products. PMA member companies produce the vast majority of the prescription medicines used in the United States. They annually invest more than $8 billion in research and development. This substantial private research effort is the source of virtually all new drugs marketed in the United States.

The American Medical Association (AMA) is a private, voluntary, nonprofit organization of physicians. It was founded in 1846 to promote the science and art of medicine and the improvement of public health. Today, it is the largest health-care organization in the United States, representing the interests of more than 280,000 physicians and their patients in promoting the availability and quality of health care.

Amici are concerned because the threat and award of standardless and excessive punitive damage judgments against pharmaceutical manufacturers is compromising the industry's research efforts and depriving Americans of significant pharmaceutical therapies. In important areas such as childhood vaccines and drugs for pregnant women, liability concerns already have had a demonstrable negative impact both on research and on the continued availability of beneficial products to the persons who need them. These adverse deve'opments have impaired physicians' access to important and often unique pharmaceutical therapies and have thereby interfered with their ability to provide the highest possible quality of medical care to their patients.

In addition, the AMA is concerned that physicians are increasingly being confronted directly with claims for punitive damages by plaintiffs alleging malpractice. Although as a practical matter awards against health-care providers are extremely rare, the availability of unlimited punitive damages remains a serious source of anxiety for them and, like other facets of the medical malpractice crisis, excessive punitive damage awards adversely affect how physicians practice medicine.

Because of the special nature of the pharmaceutical industry, the development and distribution of new drugs have been compromised to an unusual extent by the recent explosion in punitive damage liability. Research and development are expensive, time-consuming tasks. Despite extensive testing and unusually exacting regula-

tion by the federal government, full knowledge of the risks presented by new drugs can never be gained prior to marketing. In addition, all drugs are associated with adverse events in some patients. These harms cannot be avoided regardless of the degree of care exercised by the manufacturer and the prescriber. *See* pages 7-11, *infra*.

The AMA has studied the effects of product liability on the provision of health care and found that punitive damages and other liability issues "are having a profound negative impact on the development and utilization of potentially life-saving medical technologies." [1] This brief will document the deleterious effects of standardless punitive damages on the availability of pharmaceutical products. *Amici* hope that this additional perspective will assist the Court in appreciating the need for reasonable, ascertainable constitutional standards that are applicable to the award of punitive damages.[2]

SUMMARY OF ARGUMENT

The use of prescription drug products saves thousands of lives and billions of dollars each year. New drugs are developed almost exclusively by private industry, at an average cost of more than $230 million from chemical synthesis to approval by the Food and Drug Administration. FDA requires extensive clinical testing prior to marketing, and the agency approves a drug only upon its independent determination that the benefits of the product outweigh its risks.

The pharmaceutical industry's research and drug marketing decisions are particularly vulnerable to distortion from punitive damage awards imposed without adequate

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[1] AMA Board of Trustees, "Impact of Product Liability on the Development of New Medical Technologies," at 12 (June 1988) [hereinafter cited as *AMA Report*].

[2] Pursuant to Rule 37 of the Rules of this Court, the parties have consented to the filing of this brief. Their letters of consent have been filed with the Clerk of the Court.

constitutional safeguards. All drugs are unavoidably associated with adverse events in some patients; many of these events cannot be discovered prior to widespread distribution. The inevitability of injury makes manufacturers repeated targets of lawsuits involving even the safest drugs. Those lawsuits now routinely include multi-million dollar claims for punitive damages, and such punitive damage counts skew the entire course of litigation, increasing both costs and settlement demands.

The result is that pharmaceutical manufacturers have been forced to withdraw beneficial products from the market and to forgo research into new products in particularly litigation-prone areas, such as vaccines and contraceptives. For example, excessive punitive damage awards have been entered in cases where the manufacturer's conduct was approved and indeed required by FDA;[3] where no scientifically plausible relation could be shown between the drug and the injury;[4] and where the plaintiff's attorney had suggested some sort of "formula" by which punitive damages should be calculated.[5]

The prospect of standardless, excessive multi-million dollar punitive damage awards thus taints the entire drug development process. *Amici* suggest that the Court's determination of the limits required by the Due Process Clause on punitive damage awards should take into account the effect of these awards on the availability of drug therapies. In particular, any award of punitive damages for lawful conduct approved in advance by the FDA must be deemed arbitrary and excessive in violation of the Due Process Clause of the Fourteenth Amendment;

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[3] *See* Wooderson v. Ortho Pharmaceutical Corp., 235 Kan. 387, 681 P.2d 1038, *cert. denied*, 469 U.S. 965 (1984) (oral contraceptive), discussed at page 20, *infra*.

[4] *See* cases involving the anti-nausea drug Bendectin, discussed at pages 20-22, *infra*.

[5] *See* Chelos v. Endo Laboratories, No. 87-0113 (Ill. App.) (anticoagulant drug Coumadin), discussed at pages 22-23, *infra*.

individual punitive damage awards should be subject to careful judicial oversight and procedural safeguards should be required in order to ensure that punitive damage awards do not disserve society's interests in the availability of pharmaceutical products; and the possibility of multiple awards for the same course of conduct must be taken into consideration.

ARGUMENT

I. THE NATURE OF THE PHARMACEUTICAL INDUSTRY MAKES IT UNIQUELY VULNERABLE TO ARBITRARY PUNITIVE DAMAGE AWARDS.

Prescription drug therapies are among the most useful and cost-effective components of medical care.[6] A number of factors, however, create special concerns in this industry with respect to liability in general and punitive damages in particular. As Justice O'Connor recently noted, "[t]he threat of * * * enormous [punitive damage] awards has a detrimental effect on the research and development of new products," including prescription drugs.[7] *Amici* suggest that, in deciding what constitutional constraints to impose on punitive damages, the Court must be conscious of the need to "vindicate the public's interest

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[6] *See, e.g., Patent Term Extension and Pharmaceutical Innovation: Hearing Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 97th Cong., 2d Sess. 131 (statement of Mr. Hutt) ("The development of new drugs, and new methods of using and making older drugs, represents the single greatest hope of this country for holding down health care costs."). Childhood vaccines, for example, have been conservatively estimated to have a benefit/cost ratio of more than ten to one. *See* Hinman, *et al.*, "The Opportunity and Obligation to Eliminate Measles From the United States," 242 J. Am. Med. Ass'n 1157 (1979); Hinman & Koplan, "Pertussis and Pertussis Vaccine: Reanalysis of Benefits, Risks, and Costs," 251 J. Am. Med. Ass'n 3109 (1984).

[7] *Browning-Ferris Industries* v. *Kelco Disposal, Inc.*, 109 S.Ct. 2909, 2924 (1989) (O'Connor, J., concurring in part and dissenting in part).

in the availability and affordability of prescription drugs." [8]

A. Drug Research And Development Is An Expensive And Highly Regulated Enterprise.

New drug development is accomplished in this country almost exclusively by private firms under close regulation by an expert federal regulatory agency, the Food and Drug Administration (FDA). Federal law establishes a system of premarket approval for new drugs to ensure that they are safe and effective.[9] Under this system, FDA, with the advice of outside medical authorities, carefully regulates the premarket testing of new drugs, the approval process, drug manufacturing, labeling and advertising, and post-approval reporting of adverse events.[10] The regulatory controls over new drugs are enforced through criminal penalties as well as civil sanctions,[11] and constitute a pervasive system of federal regulation that is unmatched in any other industry.[12]

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[8] Brown v. Superior Court (Abbott Laboratories), 44 Cal. 3d 1049, 1068, 751 P.2d 470, 245 Cal. Rptr. 412 (1988).

[9] *See* 21 U.S.C. § 355.

[10] *See* 21 U.S.C. §§ 351-355; 21 C.F.R. Parts 200 *et seq.* FDA also imposes analogous regulatory requirements on biological products such as vaccines, pursuant to section 351 of the Public Health Service Act, 42 U.S.C. § 262.

[11] *See, e.g.*, 21 U.S.C. § 333(a)(2) (felony violations punishable by imprisonment for not more than three years or a fine of not more than $10,000 or both); *id.* § 333(a)(1) (misdemeanor violations); *id.* § 332 (injunction procedings); *id.* § 334 (seizures).

[12] *See generally* Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology, "The Food and Drug Administration's Process for Approving New Drugs," 96th Cong., 2d Sess. 21 (Comm. Print 1980) [hereinafter cited as *FDA Approval Process*] ("the FDA product approval process has become far more sophisticated than the approval process for most other products and also more cumbersome").

The FDA approval process consumes an average of twelve years between the discovery and synthesis of a new chemical entity and its approval for marketing.[13] The cost of bringing a single new drug to market has been estimated at more than $230 million.[14] In addition, pharmaceutical firms bear significant business risks during the development process: only one out of every several thousand tested chemical compounds ultimately is approved for marketing.[15]

B. Prescription Drugs Inevitably Cause Harm To Some Patients.

The extensive regulation of new drugs is justified by their potential for harm.[16] As a leading medical textbook on drug therapy states, "[v]ery few physicians believe that any drug * * * is free of toxic effects." [17] FDA

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[13] *See* DiMasi, *et al.*, "The Cost of Innovation in the Pharmaceutical Industry: New Drug R&D Estimates" (1990); Young, "The Reality Behind the Headlines," in *From Test Tube to Patient: New Drug Development in the United States* (Jan. 1988), at 5 [hereinafter cited as *New Drug Development*]. The author was Commissioner of Food and Drugs.

[14] *See* DiMasi, *supra*; *see also* Wiggins, "The Cost of Developing a New Drug" (PMA 1987); Cohn, "The Beginnings: Laboratory and Animal Studies," in *New Drug Development, supra*, at 9; *Drug Price Competition and Patent Term Restoration Act of 1984: Hearing Before the Senate Comm. on Labor and Human Resources*, 98th Cong., 2d Sess. 106 (1984).

[15] *See Innovation and Patent Law Reform: Hearings Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the House Comm. on the Judiciary*, 98th Cong., 2d Sess. 1206 (1984). Even among the compounds that survive preclinical testing and are then tested in humans, only 20% ultimately are approved. *See* Flieger, *"Testing in 'Real People,'"* in *New Drug Development, supra*, at 14.

[16] Federal law expressly refers to the "toxicity or other potentiality for harmful effect" of prescription drugs. 21 U.S.C. § 353(b)(1)(B).

[17] A. Gilman, *et al.*, *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 59 (7th ed. 1985) [hereinafter cited as *Goodman and Gilman*].

agrees that "there is no such thing as absolute safety in drugs."[18] For example, at least 300 persons die each year from anaphylactic reactions to penicillin.[19] Prescription drugs are perhaps the clearest example of products that are "unavoidably unsafe" as defined in comment *k* to section 402A of the *Restatement (Second) of Torts*.[20]

[18] *Hearings on Drug Safety Before the Subcomm. on Intergovernmental Relations of the House Comm. on Government Operations*, 88th Cong., 2d Sess., pt. 1, at 147 (1964) (testimony of former FDA Commissioner Larrick) [hereinafter cited as *Drug Safety Hearings*].

[19] *See Goodman and Gilman, supra*, at 1135. Physicians are well-aware of the possibility of anaphylaxis following penicillin administration, and a warning concerning this reaction is prominently featured in the drug's labeling. Nonetheless, it is impossible to predict whether a particular person will suffer such a reaction, and it can therefore be avoided for certain only by forgoing penicillin therapy altogether. The number of deaths from penicillin anaphylaxis represents only 0.001% of patients who are treated with the drug. *Id.*

[20] *See, e.g.*, Brown v. Superior Court (Abbott Laboratories), 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988). Comment *k* provides:

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warnings, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but

FDA makes an expert determination of whether a new drug's benefits outweigh its risks before approving the drug for marketing:

> Although no provision of the Federal Food, Drug, and Cosmetic Act provides that the FDA may approve a drug only if the benefits outweigh the risks, this inevitably is the crux of any decision to permit a new drug to be marketed or to allow an old one to remain on the market.[21]

This risk-benefit determination is made on the basis of all available information, but that information is necessarily incomplete. Despite premarket clinical testing in thousands of patients, many reactions are so rare that typically one-half or more of a new drug's adverse reactions cannot be discovered until after it is on the market and in widespread use.[22] As the Institute of Medicine observed with respect to new childhood vaccines, "it will be exceptionally difficult to define the frequency (if any)

> such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A, comment *k* (emphasis in original).

[21] Merrill, "Compensation for Prescription Drug Injuries," 59 Va. L. Rev. 1, 10 (1973), *citing Drug Safety Hearings, supra*, at 150. The author is a former FDA Chief Counsel. *Accord, Goodman and Gilman, supra*, at 57; Farley, "Benefit vs. Risk: How FDA Approves New Drugs," in *New Drug Development, supra*, at 27. FDA's risk-benefit determination is grounded in the statutory requirements that new drugs be safe and effective. *See FDA Approval Process, supra*, at 21.

[22] *See Goodman and Gilman, supra*, at 51; Merrill, "Compensation for Prescription Drug Injuries," *supra*, 59 Va. L. Rev. at 10.

of rare but potentially catastrophic reactions without administration of the vaccine to millions of children." [23] In addition, beyond the sheer difference in numbers involved, clinical trials are limited in their predictive capabilities because controlled experimental conditions are not duplicated in the typical physician's day-to-day practice.[24]

Accordingly, pharmaceutical manufacturers place their products on the market with full knowledge that some persons unavoidably will be injured, that the number of injured persons could well be quite large once hundreds of thousands or millions of persons are prescribed a particular drug in the regular course of medical practice, and that not all of the drug's possible adverse reactions have in fact been identified in the clinical trials. FDA's approval certifies that an unbiased expert regulatory body has concluded that these risks are outweighed by the drug's therapeutic benefits, and thus represents society's judgment that a particular drug should in fact be marketed.

In making this judgment, FDA must take into account not only the possibility of adverse reactions if a drug is marketed, but also the many thousands of lives that could be endangered and even lost if a drug is *not* approved for use. FDA has been extraordinarily conservative in approving new drugs, and in fact many important therapies are not made available in the United States until years after they have been approved in other western countries.[25] As a congressional report observed:

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[23] 1 Institute of Medicine, *New Vaccine Development: Establishing Priorities* 179 (1985).

[24] *See Goodman and Gilman, supra,* at 51 ("The results of clinical trials * * * may have severe limitations in terms of what can be expected of drugs when they are used in an office practice.").

[25] *See, e.g.*, General Accounting Office, "FDA Drug Approval—A Lengthy Process That Delays the Availability of Important New Drugs" (1980). FDA recently issued an interim rule "designed to speed the availability of new therapies for desperately ill patients, while preserving appropriate guarantees for safety and effectiveness." The agency recognized that "physicians and patients are generally willing to accept greater risks or side effects from products that treat life-threatening and severely-debilitating illnesses, than they would accept from products that treat less serious diseases." FDA, "Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Procedures for Drugs Intended To Treat Life-Threatening and Severely Debilitating Illnesses," 53 Fed. Reg. 41516 (Oct. 21, 1988).

> [D]elays in the approval of a drug deprive the sick from medicines which are life-saving, reduce suffering, and/or help maintain a productive life. Therefore, any protection conferred by delaying the introduction of new drugs must be weighed against the therapeutic losses incurred by delaying effective new therapies.[26]

Limited testing cannot proceed indefinitely without endangering many more lives than might be saved by a more complete data base. There comes a point when the agency, in its expert judgement, concludes that a drug presents a sufficiently favorable benefit-risk profile that it ought to be made available generally to physicians and their patients.

C. The Routine Presence Of Punitive Damage Counts And The Absence Of Standards Have Particularly Undesirable Consequences For Pharmaceutical Product Liability Litigation.

Despite the societal judgment that a drug should be marketed, the inevitability of injury assures that pharmaceutical manufacturers will be repeated targets of personal injury actions. And while extensive federal oversight and the standards of the health-care industry can be expected to ensure that the sort of reprehensible con-

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[26] *FDA Approval Process, supra,* at 31. This report provides examples of delays in the approval of important cardiovascular, neurological, respiratory, gastrointestinal, cancer, and other drugs. *See id.* at 35-51.

duct meriting punitive damages will be rare,[27] plaintiffs' lawyers apparently feel otherwise.[28] In fact, punitive damage counts have become a routine feature of complaints against pharmaceutical manufacturers.[29]

The mere presence of punitive damage counts has a pernicious effect on the entire course of drug product liability litigation. As is true with respect to many other industries, these counts are only rarely dismissed on summary judgment and typically survive to trial. Punitive damage claims therefore have caused dramatic rises in settlement costs and in litigation costs generally for pharmaceutical manufacturers. The unique nature of pharmaceutical litigation, however, gives rise to especially undesirable consequences from punitive damage claims in lawsuits involving these products.

For example, drug product liability cases raise complex medical questions that are extraordinarily difficult for lay juries to resolve, guided as they are only by their common sense and the opposing testimony of experts retained by the parties. Juries in pharmaceutical cases are

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[27] *See, e.g.*, Roginsky v. Richardson-Merrell, Inc., 378 F.2d 832, 840-841 (2d Cir. 1967) ("A manufacturer distributing a drug to many thousands of users under government regulation scarcely requires this additional measure [*i.e.*, punitive damages] for manifesting social disapproval and assuring deterrence.") (Friendly, J.).

[28] *See generally* P. Huber, *Liability: The Legal Revolution and Its Consequences* 129 (1988) ("Before long, juries were levying punitive damages, ostensibly grounded in outrageous misconduct, for acts that federal regulators had specifically contemplated and approved.").

[29] A review of reported pharmaceutical product liability cases reveals the following. During the period 1970-1979, claims for punitive damages are reflected in six decisions, fewer than one per year. During the next five years (through 1984), 17 such decisions have been found, a six-fold increase. This number has more than doubled again to 35 reported decisions during the period 1985-1988, an incidence approximately 15 times greater than in the 1970s.

therefore particularly susceptible to being "unfairly influenc[ed]" in their determination of liability for (and the amount of) compensatory damages by "irrelevant and prejudicial factors" relating solely to punitive damages.[30] In addition, the inevitability of injury—which is generally well-documented in the pharmaceutical manufacturer's files[31]—may be regarded by the jury as evidence of obduracy or even malice on the part of the defendant, increasing the likelihood that punitive damages may be awarded.[32]

While the harm resulting from a single excessive punitive damage award is a serious concern, the nature of the pharmaceutical industry is such that, as a matter of course, manufacturers face multiple claims for punitive damages from the same product. The unavoidably unsafe nature of pharmaceutical products and the large numbers of persons who use these products predictably result in numerous lawsuits with respect to any particular drug. The manufacturer may therefore be exposed to "potentially ruinous"[33] multiple punitive damage claims arising out of what is essentially a single course of conduct. These claims arise in many different states and are subject to decision under many different legal standards.

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[30] H.R. Rep. 908, 99th Cong., 2d Sess., pt. 1, at 28 (1986) [hereinafter cited as *House Vaccine Report*]. Congress has therefore recently provided for trifurcated trials in cases involving certain childhood vaccines administered after October 1, 1988. *See* 42 U.S.C. § 300aa-23 (trials conducted in three stages: liability, general damages, and punitive damages).

[31] Manufacturers must develop and retain extensive information on drug adverse events. *See* 21 C.F.R. §§ 312.32-312.33, 314.80.

[32] *See* P. Huber, *supra*, at 120 (Manufacturers have come to be regarded as "close to malevolent in their callousness: They *knew* accidents like this were going to happen, but they still declined to take measures needed to prevent the latest one.") (emphasis in original).

[33] Jeffries, "A Comment on the Constitutionality of Punitive Damages," 72 Va. L. Rev. 139 (1986).

More than twenty years ago, Judge Friendly first described the "legal difficulties engendered by claims for punitive damages on the part of hundreds of plaintiffs" in pharmaceutical litigation.[34] The lower courts have failed to agree on any coherent solution to these "staggering" [35] difficulties. While this case does not present the multiple-claimant problem as starkly as it arises in drug product liability actions, we urge that the Court's development of standards under the Due Process Clause must take into account the special dangers inherent in such a situation.

* * * *

In summary, the nature of the pharmaceutical industry makes punitive damages singularly inappropriate as well as particularly burdensome. At every step of the drug research and development process, a balance must be struck between unavoidable risks and health-care benefits.[36] The balance is struck in the first instance by the manufacturer, is subject to careful scrutiny and *de novo* determination by an expert regulatory body, and is then individualized for each patient by the prescribing physician.

Private investment decisions totaling billions of dollars annually and directly affecting the quality and cost of health care in this nation rest on how this balance is struck. Excessive, routine punitive damage claims and standardless awards—stripped from their historical con-

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[34] Roginsky v. Richardson-Merrell, Inc., 378 F.2d 832, 839 (2d Cir. 1967).

[35] *Id.*

[36] *See, e.g., FDA Approval Process, supra,* at 51:

> It must be remembered that all drugs have serious potential side effects and all drugs are capable of serious harm if misused or abused. Therefore, safety is relative and both patients and regulators must assume some risk. Levels of public expectations and regulatory goals must be modified to appreciate the necessary balancing of benefits and risks in advancing new and effective drug therapies.

text of punishing rare, outrageous conduct—skew the balance by introducing a wild card: the possibility that multi-million dollar penalties might be imposed by lay juries for perfectly lawful conduct involving beneficial medicines. As we discuss below, the distortion introduced by "skyrocketing" punitive damage claims and awards has deprived patients of significant existing therapies and has inhibited research and development concerning new therapies.[37]

II. STANDARDLESS PUNITIVE DAMAGE AWARDS AND CLAIMS HAVE ADVERSELY AFFECTED THE AVAILABILITY AND DEVELOPMENT OF PHARMACEUTICAL THERAPIES.

A recent report of the AMA Board of Trustees found that the system for determining liability, of which punitive damages is a significant part, is "having a profound negative impact on the development of new medical technologies." [38] The report continued:

> Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance. Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of safety or efficacy, but because product liability suits have exposed manufacturers to unacceptable financial risks.[39]

An FDA expert advisory panel,[40] the American Academy

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[37] *Browning-Ferris, supra,* 109 S. Ct. at 2924 (O'Connor, J., concurring in part and dissenting in part).

[38] *AMA Report, supra,* at 1. Although the Board of Trustees did not focus exclusively upon the punitive damages component of the liability system, there is no question that punitive damages play a major role in causing the "negative impact" on medical technology decried by the Board in its report.

[39] *Id.*

[40] FDA, "Biological Products: Bacterial Vaccines and Toxoids; Implementation of Efficacy Review," 50 Fed. Reg. 51002, 51006

of Pediatrics,[41] the Institute of Medicine,[42] and commentators[43] agree that these concerns have impeded pharmaceutical research and development.

A robust private resarch effort is desirable not only to discover therapies for presently untreatable diseases, but also to improve upon existing drugs by finding safer and more effective alternatives.[44] By inhibiting medical research, standardless punitive damages and other liabiiity concerns unduly restrict the physician's armamentarium and consequently the patient's prospects for recovery. These issues have been especially significant with respect to vaccines, contraceptives, and drugs for pregnant women, as we document below.

A. Vaccines

Vaccines, particularly those for childhood diseases, "are one of the great success stories of medicine."[45] Most

(Dec. 13, 1985) ("attempts to improve vaccines further will be hampered" by tort liability) (report of the Advisory Panel on Review of Bacterial Vaccines and Toxoids).

[41] *Vaccine Injury Compensation: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong., 2d Sess. 115 (1986) (statement of Dr. Martin H. Smith, President, American Academy of Pediatrics) ("research efforts for new and improved vaccines have been chilled" because of liability concerns).

[42] Institute of Medicine, *Vaccine Supply and Innovation* 11 (1985) ("apprehensions [concerning liability] are a disincentive to investment in the development of new (or improved) immunizing agents") [hereinafter cited as *Vaccine Supply*]; *id.* at 2 (resolution of liability issues necessary so that "the potential of new technologies [may] be fully realized").

[43] *E.g.*, P. Huber, *supra*, ch. 10.

[44] *See, e.g., id.* at 160-161 ("[N]ewer is generally safer than older in the modern technological world. * * * There is hardly a product in use today [including drugs and vaccines] that is not many times safer than its counterpart of a generation or even a decade ago.").

[45] *AMA Report, supra*, at 6. *See also, e.g., House Vaccine Report, supra*, pt. 1, at 4 (childhood immunization is "one of the most

domestic manufacturers, however, have stopped producing and distributing childhood vaccines.[46] More than half of the vaccine producers licensed in 1968 have ceased production,[47] and this country is now "heavily dependent on sole suppliers" for many pediatric vaccines.[48] The primary cause of this precipitous decline in our vaccine production capacity has been "the liability situation and its consequences (i.e., litigation costs or difficulty in obtaining insurance coverage)."[49]

The vaccine liability crisis is well-established. There are hundreds of suits pending, with damage claims, including punitive damages, totaling several billion dollars.[50] This figure is more than 10 times the annual

spectacularly effective public health initiatives this country has ever undertaken," having "prevented thousands of children's deaths each year" and saved "[b]illions of medical and health-related dollars").

[46] *See, e.g., id.* In addition, foreign manufacturers are reluctant to enter the United States market because of liability concerns. *See, e.g., Vaccine Supply, supra*, at 5.

[47] *Id.* at 46.

[48] *Id.* at 5. *See also House Vaccine Report, supra*, pt. 1, at 7 ("Currently, there is only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, rubella (MMR) vaccine, and two manufacturers of the [pertussis] vaccine.").

[49] *Vaccine Supply, supra*, at 11.

[50] *See, e.g.*, Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, "Childhood Immunizations, 99th Cong., 2d Sess. 85-86. An illustrative case is Johnson v. American Cyanamid Co., 239 Kan. 279, 718 P.2d 1318 (1986). There, a jury awarded the plaintiff $10 million in damages, including $8 million in punitive damages, for injuries arising out of administration of the Sabin live-virus polio vaccine. The basis for the complaint was that use of the Salk killed-virus vaccine rather than the Sabin vaccine would have prevented the plaintiff's injury. The enormous punitive damage award was imposed, notwithstanding the conclusion of federal public health experts and other medical authorities that the Sabin vaccine is superior and the manufacturer's reliance on governmental immunization initiatives recom-

sales for the entire vaccine industry.[51] In short, routine punitive damage claims require manufacturers "to engage in a gamble with very large financial stakes. * * * The only way to eliminate the risk is to stop manufacturing the vaccine."[52] As discussed above, that is precisely what most manufacturers have done.[53]

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mending the production and use only of the Sabin vaccine. The judgment ultimately was set aside on appeal, but only by the narrowest of margins in the Supreme Court of Kansas (4-3). The fact that a punitive damage claim could seriously be entertained in these circumstances, much less survive through trial and virtually through appeal as well, is clear evidence of the liability risks and litigation costs that are borne by vaccine manufacturers as a result of the lack of ascertainable standards governing imposition of punitive damages.

[51] *See Vaccine Supply, supra,* at 45-46. *See also* P. Huber, *supra,* at 166-167 ("In 1986, a new claim was being filed against the manufacturers of whooping cough vaccine every week; one former manufacturer faced 100 suits demanding more than $2 billion in compensation, or 200 times the total annual sale revenues of the vaccine.").

[52] *Vaccine Supply, supra,* at 10, 117-118.

[53] Congress recently acted to establish a compensation system for persons injured by certain childhood vaccines. *See* National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C. §§ 300aa-1 *et seq.* Under this system, persons dissatisfied with a no-fault award from a compensation fund may reject the award and sue the manufacturer, but punitive damages may not be awarded in the absence of proof that the manufacturer wrongfully withheld information from FDA or engaged in similar unlawful conduct. 42 U.S.C. § 300aa-23(d)(2). Congress expressly found that punitive damages should not otherwise be imposed:

> Where a manufacturer has attempted in good faith to comply with a government standard—even if the standard provides inadequate protection to the public—the manufacturer should not be assessed punitive damages absent evidence that it engaged in reprehensible behavior that directly resulted in the [initial or continued approval of the vaccine].

House Vaccine Report, supra, pt. 1, at 28. White salutary, this development is unfortunately of limited utility. It covers only a small number of vaccines, and even as to those it applies only to claims arising out of administrations after October 1, 1988. The

Most recently, the manufacturer of the vaccine for Japanese encephalitis ceased distribution because it could not obtain "appropriate liability insurance, and there was no statutory mechanism for absolving it of liability."[54] The unavailability of the vaccine put Americans traveling to certain areas of Asia at increased risk for this disease.

B. Contraceptives And Drugs For Pregnant Women

The adverse impact of excessive punitive damage claims and awards also has been keenly felt by manufacturers of contraceptives and drugs for pregnant women. A recent study by the National Research Council and the Institute of Medicine concluded that product liability concerns "have contributed significantly to the climate of disincentives for the development of contraceptive products."[55] The study emphasized in particular the "unpredictable nature of litigation" and the failure of the courts to give sufficient weight to "evidence of compliance with FDA regulations."[56]

The AMA also has documented the dramatic drop in basic research in this area:

> In the early 1970s, there were 13 pharmaceutical companies actively pursuing research in contraception and fertility. Now, only one US company conducts contraceptive and fertility research. Unless the liability laws are drastically altered, it is very

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statute does not and was not intended to address the larger constitutional issues concerning the award of punitive damages in pharmaceutical cases.

[54] Marcus, "Liability for Vaccine-Related Injuries," 318 N. Eng. J. Med. 191 (1988).

[55] National Research Council & Institute of Medicine, *Developing New Contraceptives—Obstacles and Opportunities* 141 (L. Mastroianni, *et al.,* eds. 1990).

[56] *Id.*

unlikely that pharmaceutical companies will aggressively pursue research in this area.[57]

Another study confirms that private domestic research expenditures on contraceptives declined by 90% in the decade following their peak in 1973, and that "no truly new contraceptive chemical entities have been introduced since 1968." [58] Innovation also has virtually ceased with respect to drugs for use by pregnant women, again because of liability concerns.[59]

The observation that "punitive damages are out of control" [60] is perhaps nowhere as apt as in these areas. In *Wooderson* v. *Ortho Pharmaceutical Corp.*,[61] for example, the plaintiff was awarded $4.75 million in damages, including $2.75 million in punitive damages, for kidney damage alleged to have been caused by an oral contraceptive. The award was upheld, even though the FDA had expressly refused to approve the addition of a warning because of the lack of scientific evidence supporting causation and the defendant could have been in violation of federal law had it done so.[62]

The loss of valuable therapies as a result of punitive damages and other liability concerns is particularly striking in the case of Bendectin, an anti-nausea medication useful for pregnant women. Notwithstanding the "nearly universal consensus" that Bendectin does not cause birth defects,[63] the manufacturer was besieged by lawsuits and

[57] *AMA Report, supra*, at 9.

[58] P. Huber, *supra*, at 155.

[59] *See id.*

[60] Jeffries, *supra*, 72 Va. L. Rev. at 139.

[61] 235 Kan. 387, 681 P.2d 1038, *cert. denied*, 469 U.S. 965 (1984).

[62] *See* Brief Amicus Curiae of the PMA in Support of Petition for a Writ of Certiorari, No. 84-290, at 14-19.

[63] Richardson v. Richardson-Merrell, Inc., 649 F. Supp. 799, 803 (D.D.C. 1986), *aff'd*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989). Following public hearings and an extensive review of the evidence, FDA's Fertility and Maternal Health Drugs Advisory Committee—an independent expert panel composed of physicians, scientists and a consumer representative, and advised by scientists from the National Institutes of Health—concluded in 1980 that there is no increased incidence of birth defects resulting from exposure to Bendectin. FDA announced its agreement with this finding, and the agency has stood by it ever since. *See id.*

When the scientific studies have been presented dispassionately at trial, untainted by the understandably moving evidence of the children's birth defects or by evidence purportedly going to punitive damages, the jury has determined that Bendectin does not cause birth defects. *See* In re Bendectin Litigation, 857 F.2d 290 (6th Cir. 1988), *cert. denied*, 109 S. Ct. 788 (1989) (in 22-day trifurcated trial of more than 800 consolidated cases, solely on the issue of causation, jury concluded that plaintiffs had not established that Bendectin is a proximate cause of human birth defects).

ultimately ceased distribution of the product in 1983.[64] Punitive damage claims have been a routine part of Bendectin litigation, and jury awards of such damages are disconcertingly common, while the judicial response has been inconsistent.[65] The litigation surrounding Ben-

[64] *See, e.g.*, Richardson v. Richardson-Merrell, Inc., 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989).

[65] For example, the jury in Ealy v. Richardson-Merrell, Inc., No. 83-3504 (D.D.C. Oct. 1, 1987), awarded $75 million in punitive damages, which the district court remitted in its entirety because of the lack of any evidence of wrongful conduct on the part of the defendant. The court of appeals in *Ealy* subsequently held that judgment n.o.v. should have been granted to the manufacturer with respect to liability for both compensatory damages and punitive damages. Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159 (D.C. Cir. 1990). Other trial courts, however, have upheld punitive damage awards in Benedectin cases. *See* Blum v. Merrell Dow Pharmaceuticals, Inc., 1 Pa. D. & C. 4th 634 (Penn. Ct. of Common Pleas 1988), *rev'd in part and aff'd in part*, 385 Pa. Super. 151, 560 A.2d 212 (1989); Brock v. Merrell Dow Pharmaceuticals, Inc., No. L-83-148-CA (E.D. Tex. Mar. 4, 1988), *rev'd*, 874 F.2d 307, *mod.*, 884 F.2d 166, *reh'g denied*, 884 F.2d 167 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990). Trial on the issue of punitive damages in another Bendectin case has been postponed pending this Court's decision here. *See* Oxendine v. Merrell Dow Pharmaceuticals, Inc., No. 1245-82 (D.C. Super. Ct. Apr. 19, 1990).

dectin has ill-served the patient population. As the American College of Obstetricians and Gynecologists concluded, the loss of Bendectin " 'creates a significant therapeutic gap' " for the treatment of pregnant women, and in its absence " 'severe cases [of nausea and vomiting during pregnancy] have led to serious maternal nutritional as well as other deficiencies.' " [66]

C. Other Drug Products

Many other drug products have been the subject of standardless multi-million dollar punitive damage awards and routine claims for such amounts. These cases confirm the lessons from the products already discussed: punitive damages are imposed on facts far removed from what historically was required for such extraordinary awards, they distort incentives for research and development, and they ultimately deprive patients of significant pharmaceutical therapies.

In a case involving the widely-prescribed anti-coagulant drug Coumadin (warfarin sodium), for example, a jury awarded more than $26 million in punitive damages for injuries resulting from a necrotic reaction, a rare and unavoidable side effect.[67] Although the FDA-approved package insert warned of necrosis, the plaintiff argued that the warning should have been more specific and that additional reports should have been made to the agency. The plaintiff further suggested to the jury a formula for determining punitive damages, amounting to 20-30 cents per day for each person purportedly at risk for the reaction as a result of Coumadin therapy during the years 1965 through 1977. The $26 million punitive damage award, which the trial court later remitted to $13 mil-

[66] *AMA Report, supra,* at 11 (citation omitted).

[67] Chelos v. Endo Laboratories, Inc., No. 87-0113 (Ill. App.). The case was settled on confidential terms before argument in the Appellate Court.

lion, fell within the range resulting from reliance on the plaintiff's formula.

The threat of punitive damage awards adversely affects the availability of important new therapies even where no awards involving a particular product actually have been entered. For example, distribution of the drug botulinum, the only available treatment for certain eye conditions, was temporarily halted during clinical investigations as a result of liability concerns.[68] Similarly, small biotechnology firms, which often are at the cutting edge of innovation, have reported that product liability issues have a significant, untoward impact on decisions concerning research and commercial development of new products.[69]

III. CONSTITUTIONAL STANDARDS CIRCUMSCRIBING THE AWARD OF PUNITIVE DAMAGES ARE NECESSARY.

While the case before the Court may appear far removed from the context of pharmaceutical product liability litigation, the Court's decision will undoubtedly have a significant effect on this litigation. A refusal to undertake demanding constitutional scrutiny of punitive damage awards under the Due Process Clause would send precisely the wrong message: that pharmaceutical manufacturers are fair game for whatever multi-million dollar awards can be coaxed from sympathetic juries or

[68] *See AMA Report, supra,* at 11. The product ultimately was approved for commercial distribution.

[69] *See id.* The loss of beneficial products can occur without actually driving a particular manufacturer entirely out of business. It is enough if the threat or award of punitive damages causes a defendant to abandon a particular product or class of products. If an important pharmaceutical therapy is lost, it does not matter whether it is lost because punitive damages have ruined a small producer or have caused a larger company to abandon the product or area in favor of less risky avenues of research and development. In either case, the negative impact on the public health is the same.

pried from defendants in settlement. That message has been sent repeatedly by the lower courts. Should it receive this Court's imprimatur, the distorting effect of excessive punitive damages will be substantially increased.[70] The predictable result will be needless losses to patients, as beneficial therapies are withdrawn from the market and pharmaceutical research and development expenditures are directed toward other areas.

Amici suggest that the constitutional standards enunciated by the Court in this case should take account of three issues particularly relevant to the pharmaceutical industry. These concerns are directly pertinent to the protections " 'against arbitrary action of government' " embodied in the Due Process Clause.[71]

First, punitive damage awards are arbitrary and excessive, in violation of the Due Process Clause, when they are awarded for conduct that not only is lawful, but was specifically approved in advance by the responsible government agency. Under this principle, unusually close constitutional scrutiny is appropriate in the pharmaceutical field because the defendant has engaged in lawful conduct approved by an expert regulatory body. Absent clear proof that the defendant committed an unlawful act in regard to obtaining FDA approval, which was material to the harm in question, any punitive damage award is improper in relation to the conduct of the

[70] The need for guidance under the Due Process Clause is particularly important in light of the Court's decision last Term in *Browning-Ferris* that the Eighth Amendment does not apply to punitive damage awards. The Court was careful to note in that case that it was not foreclosing due process challenges to such awards. *See Browning-Ferris, supra*, 109 S. Ct. at 2921; *id.* at 2923 (Brennan, J., concurring); *id.* at 2924 (O'Connor, J., concurring in part and dissenting in part).

[71] *Browning-Ferris, supra*, 109 S. Ct. at 2923 (Brennan, J., concurring) (citation omitted).

pharmaceutical manufacturer in placing an approved drug on the market.[72]

Second, punitive damage awards are arbitary when they discourage basic pharmaceutical research and lead to the withdrawal of beneficial therapies. Each individual award must be assessed in this light to protect the interests of all patients. Substantive standards and procedural safeguards are required to ensure that juries and judges do not render and approve inappropriate punitive damage awards. It would be useful, for example, to require more detailed guidance in jury instructions than was provided in this case;[73] to impose a heightened burden of proof, such as clear and convincing evidence, for the award of punitive damages;[74] and to bifurcate trials, with proceedings on punitive damages conducted separately from issues pertaining to basic liability and the amount of compensatory damages.[75] Appropriate general standards under the Due Process Clause are discussed in the brief of *amici* United States Chamber of Commerce *et al.*

[72] Five states have enacted defenses to punitive damages for pharmaceutical manufacturers that have complied with relevant FDA approval and reporting requirements. *See* Ariz. Rev. Stat. § 12-701; N.J. Stat. Ann. § 2A:58C-5(c); Ohio Rev. Code Ann. § 2307.80; Or. Rev. Stat. § 30.927; Utah Code Ann. § 78-18-2. There is a similar federal defense in cases arising out of administration of childhood vaccines. *See* 42 U.S.C. § 300aa-23(d)(2); note 53, *supra*.

[73] *See Browning-Ferris, supra*, 109 S. Ct. at 2923 (Brennan, J., concurring) (criticizing "skeletal guidance" to jurors that amounts to "little more than an admonition to do what they think is best"); Bankers Life & Casualty Co. v. Crenshaw, 486 U.S. 71, 88 (1988) (O'Connor, J., concurring in part and concurring in the judgment) (a "grant of wholly standardless discretion to determine the severity of punishment appears inconsistent with due process").

[74] *Cf.* Santosky v. Kramer, 455 U.S. 745 (1982) (requiring proof by clear and convincing evidence in civil custody proceedings).

[75] *Cf.* 42 U.S.C. § 300aa-23 (requiring trifurcated trials, with separate proceedings on liability, the amount of compensatory damages and the amount of punitive damages, in vaccine cases).

Third, where a single product or course of conduct may give rise to multiple claims for punitive damages, particularly careful judicial scrutiny is required.[76] Pharmaceutical manufacturers are especially vulnerable to such multiple claims because their products are used by thousands or millions of patients, and injuries to some of them are unavoidable.

CONCLUSION

The judgment of the Supreme Court of Alabama should be reversed.

Respectfully submitted,

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May 31, 1990

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[76] *See* Juzwin v. Amtorg Trading Corp., 705 F. Supp. 1053 (D.N.J. 1989). The court granted a motion for reconsideration of this decision with respect to the remedy that had been fashioned, but it adhered to "its previous ruling that repetitive awards of punitive damages for the same conduct violate a defendant's due process rights." Juzwin v. Amtorg Trading Corp., 718 F. Supp. 1233, 1234 (D.N.J. 1989).